CLAIMS

1.   An agent for the diagnosis or treatment of those tumours that in an individual patient expose on the cell surface only a number n smaller than N of N different altered forms that a given protein or glycoprotein of said tumour type can assume in a population of patients, said altered forms of the protein deriving from alterations of a normal form present in healthy tissue, said agent comprising:

a.   a recognition unit consisting of a conjugate of m recognition molecules, where m is at least 2 and equal or smaller than n, and each recognition molecule is specific for a different altered form of the protein, and,

b.   at least one unit which supplies a diagnostic signal or therapeutic effect, conjugated with or included in said specific recognition unit.

2.   An agent as claimed in claim 1, wherein the recognition molecules are selected from among immunoglobulins or fragments thereof, polypeptides and polysaccharides.

3.   An agent as claimed in claim 2, wherein at least one recognition molecules is an Fab, F(ab') or scFv fragments.

4.   An agent as claimed in claim 2 or 3, wherein the recognition molecules are conjugated to one another by means of a direct covalent bond or by means of a multipurpose linker able to form covalent bonds with the molecules, and/or as a result of the expression of fused genes with suitable linker regions.

5.   An agent as claimed in any one of claims 1-4, wherein at least one of the specific recognition molecules recognises a protein altered as a result of one or more mutations.

6.   An agent as claimed in any one of claims 1-4, wherein at least one of

the specific recognition molecules recognises a protein altered as a result of post-translational modifications, deficient post-translational modifications, absence of post-translational modifications or partial degradation.

7.   An agent as claimed in any one of claims 1-6, wherein one of the specific recognition molecules recognises an E-cadherin with a deletion in exon 8 and another molecule recognises E-cadherin with a deletion in exon 9.

8.   An agent as claimed in any one of the preceding claims, wherein the unit able to provide a diagnostic signal or therapeutic effect is linked directly, via an avidin/biotin or streptavidin/biotin system or via a suitable covalent linker to one of the recognition molecules of the recognition unit, or to the linker that holds the recognition molecules together.

9.   An agent as claimed in claim 8, wherein the unit able to provide a diagnostic signal or therapeutic effect is conjugated covalently with biotin, and the recognition unit is conjugated covalently with avidin or streptavidin.

10.   An agent as claimed in claim 8, wherein the unit able to provide a diagnostic signal or therapeutic effect is conjugated covalently with avidin or streptavidin, and the recognition unit is conjugated covalently with biotin.

11.   An agent as claimed in any one of the preceding claims, wherein the unit able to provide a diagnostic signal or therapeutic effect is part of the bond between the recognition molecules of the recognition unit.

12.   An agent as claimed in any one of the preceding claims, wherein the unit able to provide a diagnostic signal or therapeutic effect is a radioactive halogen, a chelate of an radioactive isotope, a chelate of a paramagnetic metal ion, a stabilized particle of iron oxide, a stabilised microbubble, a fluorescent, phosphorescent or near-infrared radiation-absorbing compound, a cytotoxic compound, a natural or synthetic toxin, or a photodynamic compound able to generate reduced oxygen species or singlet oxygen by irradiation.

13.   An agent as claimed in claim 12, wherein the radioactive halogen is

selected from ^{123}I, ^{124}I, ^{125}I, ^{131}I, ^{75}Br, ^{76}Br, ^{77}Br and ^{82}Br.

14.   An agent as claimed in claim 12, wherein the radioactive isotope is selected from among ^{99m}Tc, ^{111}In, ^{203}Pb, ^{66}Ga, ^{67}Ga, ^{68}Ga, ^{161}Tb, ^{72}As, ^{113m}In, ^{97}Ru, ^{62}Cu, ^{64}Cu, ^{67}Cu, ^{52}Fe, ^{52m}Mn, ^{51}Cr, ^{186}Re, ^{188}Re, ^{77}As, ^{90}Y, ^{169}Er, ^{121}Sn, ^{127}Te, ^{142}Pr, ^{143}Pr, ^{198}Au, ^{199}Au, ^{109}Pd, ^{165}Dy, ^{149}Pm, ^{151}Pm, ^{153}Sm, ^{157}Gd, ^{159}Gd, ^{166}Ho, ^{172}Tm, ^{169}Yb, ^{175}Yb, ^{177}Lu, ^{105}Rh, ^{111}Ag, ^{47}Sc, ^{140}La, ^{211}At, ^{212}Bi, ^{213}Bi, ^{212}Pb, ^{225}Ac, ^{223}Ra, ^{224}Ra and ^{227}Th.

15.   An agent as claimed in claim 12, wherein the paramagnetic metal is selected from the metal elements having an atomic number of 21-29, 39, 42, 44, 49 or 57-83.

16.   An agent as claimed in claim 15, wherein the metal is selected from among Gd^{3+}, Fe^{3+}, Eu^{3+}, Dy^{3+}, La^{3+}, Yb^{3+} and Mn^{2+}.

17.   An agent as claimed in claim 15 or 16, wherein the metal or isotope is chelated by chelating groups deriving from diethylenetriamine or from polyamine macrocycles, both substituted by residues bearing carboxy, phosphonic or sulphonic groups.

18.   An agent as claimed in any one of claims 1 to 17, wherein the various recognition molecules are conjugated to one another, or said recognition molecules are conjugated with the therapeutic or diagnostic unit, by reaction between sulfhydryl-reactive groups and the sulfhydryl groups present, or generated by reduction of disulfide bridges, on said units/molecules.

19.   Pharmaceutical or diagnostic compositions containing an agent as claimed in claims 1-18, in admixture with a suitable vehicle.

20.   Compositions as claimed in claim 19, in the form of a kit containing:

   a.   the unit able to provide a diagnostic signal or therapeutic effect, covalently conjugated with biotin, and

   b.   a recognition unit covalently conjugated with avidin or streptavidin.

21. Compositions as claimed in claim 19, in the form of a kit containing:

    a.   the unit able to provide a diagnostic signal or therapeutic effect covalently conjugated with avidin or streptavidin, and

    b.   a recognition unit covalently conjugated with biotin.

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